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Mr. Chairman, distinguished members of the committee, I am the Director of the Johns Hopkins University Center for Civilian Biodefense Strategies. I am a physician trained in internal medicine and public health and am on the faculty of the Johns Hopkins Bloomberg School of Public Health. I have had the privilege to serve, or am now serving on a number of advisory panels related to bioterrorism including committees sponsored by the Defense Science Board, the National Academy of Sciences, the National Academy of Engineering, and the Defense Threat Reduction Agency. I appreciate the opportunity to appear before you today to discuss President Bush's proposed Department of Health and Human Services (HHS) bioterrorism related programs and budget priorities for fiscal year 2003.

I am strongly supportive of the President's FY 03 HHS budget request for bioterrorism funding. The proposed budget is unprecedented in two ways: it includes an ambitious, realistically funded and comprehensive program to upgrade the capacities of state and local public health departments to detect and respond to bioterrorist attacks, as well as a huge increase for biodefense-related research and development. I believe that the objectives and requested funding levels of both of these programs are not only appropriate, but represent essential national security expenditures.

Public Health and Medical Response

The emphasis which Secretary Thompson has placed on improving the capacity of state and local agencies to respond to bioterrorist attacks is absolutely the right priority from national security perspective. Although the terror and suffering that might be associated with biological weapons attacks has been glimpsed in the aftermath of the anthrax mailings, the true potential for civilian deaths and for economic and social disruption which these weapons hold have, fortunately, yet to be realized. It is notable that the Commission on National Security in the 21st Century chaired by former Senators Hart and Rudman cited biological weapons as possibly the "greatest security threat facing the country.

It is also important to recognize, that *a great deal can be done to mitigate the consequences of bioterrorist attacks*. Appropriate preparation on the part of the medical and public health community, coupled with effective medicines, vaccines and diagnostic technologies could significantly ameliorate the potential calamity of bioterrorist attacks on civilian populations. In this respect, biological weapons differ significantly from the threat posed by nuclear weapons. But once an attack is underway, it is too late to mount an effective bioterrorism response from scratch. The preparations and response systems have to be designed and implemented and practiced beforehand to be successful.

It is well understood that the response to a catastrophe – whether it be a natural event such as an earthquake, or a terrorist attack such as we experienced on September 11 – is and must be carried out by local authorities. The immediate aftermath of such events, before federal resources can be mustered and gotten to the scene, is critical. As we saw with the anthrax mailings, the first responders to bioterrorism threats are public health professionals, clinicians and laboratorians.

State and Local Public Health

What the proposed HHS program for upgrading local and state public health capacities attempts to do is create a program "template" for health agencies which outlines the core functions that would be needed to respond to a deliberate epidemic. State/Territory health agencies are required to submit a self-assessment of their current ability to carry out such functions as well as a plan to implement needed upgrades.

This is not a plan to improve public health across the board – the functional capacities that the plan addresses are those specifically needed to respond to biological attacks. It is also noteworthy that the proposed program integrates what are now three separate funding streams (from the Centers for Disease Control and Prevention, the Office of Emergency Preparedness, and the Health Resources and Services Administration). This integration will greatly improve fiscal and program accountability and should also enable more efficient management of bioterrorism preparedness efforts.

Hospital Preparedness

The amount requested for hospital preparedness (HRSA funds) are nowhere near sufficient to prepare the nation's 5000 hospitals to cope with mass casualty situations – i.e. contexts in which 1000 or more people need immediate medical care. Over the past decade, hospitals and health care organizations have reacted to the financial pressures on health care by shedding "excess capacity" – staff has been reduced and just-in-time models are used to manage everything from nursing rosters to medical supplies and pharmaceuticals. An HHS study reports that only 10% of hospitals surveyed could handle 50-100 patients suddenly needing care, and only 3% had conducted bioterrorism disaster drills. Unfortunately, there is no "payer" for hospital disaster preparedness, and so operational plans that would be critical in a mass casualty setting have yet to be devised or tested.

The country will eventually have to determine how to pay for creation of adequate hospital preparedness, but it makes sense at this point to invest limited funds in planning what needs to be done. It is urgent that hospitals become engaged in community wide bioterrorism response planning. Hospitals would be a critical component of any response to bioterrorism – even much of the military and all of their dependents rely on civilian hospitals. Until now, however, hospitals and health care organizations have not participated in preparedness activities. The funds requested are essential to allowing and encouraging hospitals to begin such engagement.

Sustained Funding Necessary

The HHS guidance for state health departments posits an extremely ambitious agenda. If accomplished, we will have substantially improved the country's ability to respond to a Bioterrorist attack, and make important headway in minimizing loss of life and social disruption. However, rebuilding public health – or rather, creating a public health system for the 21st century – will be a job of many years and *will require sustained funding*.

We have a long record of funding the disease or public health issue "du jour" and then abandoning these programs. For example, New York City built an excellent program to deal with West Nile Virus and then saw federal funding for these efforts cut in half once the initial anxiety and media coverage subsided. How do we avoid having such a vital national security need as bioterrorism preparedness suffer a similar fate?

HHS appears to recognize this danger and has called for states to devise performance measures and set milestones to gauge progress – presumably in order to both affirm genuine progress towards preparedness goals and to keep investments focused on Bioterrorism priorities. I hope both the Congress and governors pay close attention to these programs and their progress. Sustaining these investments – which will be difficult in the budget context states now face – is highly unlikely if states cannot demonstrate clear gains.

Need to Attract New Talent into Public Health

State and local health departments have widely different levels of Bioterrorism preparedness and functional capacity. Nonetheless, ALL are likely to need an infusion of new people to achieve an adequate skill mix and response capacity. Improving the talent base of the public health system should be a high priority, either through new hires or via on-the-job training and development.

Many states have imposed hiring freezes in response to the economic conditions and local budget constraints. It would be extremely helpful if the federal funds required waivers for such freezes.

It would also be very helpful to the federal workforce if we could find ways to allow mid-career professionals – especially experienced clinicians and public health experts – to work for federal and state agencies for one-to two years. This would provide an immediate infusion of expertise into the very stretched federal system.

Need Greater Emphasis on Communications Skills and Capacities

One relatively neglected aspect of the otherwise comprehensive preparedness program proposed pertains to the need to improve health departments' ability to communicate with the media and the public in a timely way. Health officials at state and local levels could benefit from training in how to interact effectively with the media. It would also be

advantageous to educate at least some members of media about bioterrorism issues and response plans in advance of actual attacks, and to have public health officials identify technical experts who could be available to the media during a crisis. Israel has done this with considerable success.

It is also important that health agencies develop prepared fact sheets and other materials that would be ready to go in an emergency. Prepared communications plans that are able to deliver clear messages to all facets of the community, including non-English speaking persons are also essential.

Biodefense Research and Development

The unprecedented amount of money being requested for NIH/NIAID strongly signals that the Administration understands the important role biological science and biotechnology must play in protecting national security during this new era of catastrophic terrorism.

Need for Clear R&D Strategy

Investing these funds wisely, and structuring the investment so that the country gets the products we need – e.g. effective treatments and vaccines, rapid diagnostic tests, etc.- will require a *research and development strategy*. It is not yet clear what this strategy will be – or who gets to have a say in its creation.

To its credit, the National Institutes of Health held a two-day meeting of distinguished bioscientists earlier this month to discuss potential research directions. Such openness to the professional community's ideas is commendable and useful. However, the scope of the biodefense agenda and the urgent need for success may require a more innovative and aggressive approach to managing biodefense research.

Engaging Top Scientists from Universities and the Private Sector

The United States has enormous talent in biomedical research, and of course we would like to have the best scientists involved in biodefense work. But this will not happen unless the practical aspects of the scientific enterprise are understood and taken into account.

The bulk of the talent in bioscience research works in either universities or the private sector – e.g. the pharmaceutical and biotechnology industries. University scientists are extremely reluctant to enter a new field of research without a high degree of assurance that funding in the field will be sustained. Funding concerns require that most research faculty solicit research grants years in advance. Thus, most top scientists have completely full dockets, and cannot easily change the direction of their studies on short notice. Some universities forbid classified research. The constraints of classification, as well as the costs of implementing new research security standards now under consideration may discourage some university scientists from pursuing biodefense work.

Federal funding for biodefense research is now spread across multiple agencies, making it difficult for scientists who are working on relevant topics or interested in becoming engaged in biodefense work to "plug in" to federal needs and funding opportunities. Biodefense research encompasses a rich and diverse spectrum of scientific disciplines including biology, medicine, engineering, information technology, etc. A federal clearinghouse that provided a map of contract and grant offerings would be very useful. A clear articulation of broad government priorities would also aid private sector scientists who are trying to decide if participation in government-sponsored research is worthwhile.

In addition, there are a number of legal and procedural issues that must be resolved if the private sector is to become significantly involved in biodefense R&D. These issues include intellectual property matters – which are currently treated differently by NIH and DARPA; uncertainties associated with the FDA approval process for vaccines and drugs against bioweapons agents – which cannot, for ethical reasons, be tested in humans; and concerns about federal contracts and grants processes themselves. The traditional NIH grant process, for example, requires elaborate proposals and incorporates long review times. These features make it difficult for small biotech companies, which often must move quickly to secure funding and produce product, to participate.

Need for Research in Public Health and Systems Building

NIH is the premier basic biomedical research center in the world. It has an unsurpassed record of promoting top-notch bench research in basic biology and human disease. There are, however, areas of biodefense R&D that deserve critical attention, but which fall outside NIH's traditional scope of endeavor.

For example, there is an urgent need to *develop*- not just discover or test – certain urgently needed biodefense products, such as rapid diagnostic tests, vaccines and drugs for the most likely bioweapons pathogens. The biotechnology and pharmaceutical industries have far more expertise and experience in producing such products than do federal agencies. Whether such product development should be based in NIH or in the private sector is a critical question worthy of careful deliberation. I do not have the answer to this, but our experience with vaccine production suggests it deserves focused attention.

Another essential area of research involves matters which pertain to public health practice and the design of public health systems. It is not clear if NIH intends to support this type of research, but there is no other obvious source of funding. For example, there is a clear need to develop criteria by which we could evaluate the dozens of disease surveillance systems now being proposed throughout the country. Considerable effort and money is being invested in different prototype surveillance systems aimed at providing an electronic, population-based picture of the leading edge of epidemics. The idea is to detect an attack (or a natural disease outbreak) when the initial patients first become ill, thereby facilitating early intervention, saving lives, and preventing the spread of contagious disease.

But such surveillance systems require sophisticated analytical algorithms and depend on data collection from diverse sources. In most of the systems piloted to date, such data requirements have levied heavy burdens on the involved medical and public health systems. It also remains unclear which systems – if any – significantly contribute to epidemic control. Some proposed surveillance systems would link individual medical records to credit card histories and other sensitive information, raising important questions about privacy and confidentiality. The country needs to develop ways of evaluating these systems before we waste hundreds of millions of dollars on something that doesn't work. Integration of these systems into a national level database would be highly desirable, but is unlikely to occur without federal intervention and significant investigation.

Similarly, we need research on ways to manage massive numbers of casualties without building an unsustainable infrastructure that is wasted on "normal" days. Indeed, the creating the public health system we need for biodefense involves research questions comparable in complexity to those in the basic bioscience research realm. Yet, as noted, it is unclear if NIH is to be the sponsor of such research.

Summary

The proposed HHS FY 03 bioterrorism budget is very well thought out, and of sufficient scope and size to make a meaningful improvement in bioterrorism preparedness. The proposed investments in upgrading the bioterrorism response capacities of state and local public health departments are critical to US national security. We have seen how much suffering and disruption ensued from eighteen cases of anthrax – a treatable disease. In the absence of significant improvements in our public health infrastructure, the country is vulnerable to the potentially calamitous consequences of a large bioterrorist attack.

The proposed funding streams, together with bioterrorism preparedness monies in the FY '02 HHS appropriation, constitute an important down payment on the construction of a 21st century public health system that could adequately respond to a bioweapons attack or to a large, naturally occurring outbreak of infectious disease. It is imperative that such investments be sustained over many years. The US public health system has been under funded and understaffed for decades – it will not be transformed in a year or two. As we go forward, it will be important to devise planning strategies that establish clear and reasonable expectations for future funding so that states and regions can sustain the cost of maintaining these systems in a state of readiness.

The proposed investments in biodefense R&D are also commendable and absolutely necessary. Science and technology can provide crucial tools needed to render bioweapons obsolete as weapons of mass destruction and high lethality. I would encourage the leadership of HHS and NIH to continue the open dialogue it has begun with the scientific community as it establishes priorities and directions for research. The development of R&D strategy will no doubt evolve as the science (and our understanding of the threats) progresses. An R&D strategy is needed that assigns priorities to urgent projects – such as

the pressing need for second generation anthrax vaccine, and for rapid and reliable diagnostic tests for likely bioweapons agents. Such a strategy should be developed in collaboration with the scientific community to the maximal possible extent and should take into consideration the need for research in public health as well as basic biomedical fields.

Careful consideration should be given to how the country might effectively engage the tremendous talent inherent in the university research community and in the private sector. To this end, it would be important for the government to contemplate the establishment of different types of research grants and contracts to better accommodate the needs of these different communities. Innovative organizational and funding arrangements, such as those found at DARPA or the CIA's InQTel should be investigated as possible models. The Human Genome Project - a highly successful collaboration among government and academic scientists, which pursued a very complex and specific research goal - may offer useful lessons.

I urge the Congress to fully support the Administration's funding requests for HHS bioterrorism programs in FY 03. The proposed investments in rebuilding the nation's public health infrastructure are essential to national security. The proposed biodefense research funds are likewise critical. President Bush is correct to emphasize the importance of this unconventional threat.

It should be recognized that these investments will not only better protect American civilians against terrorist attack, but will also yield additional benefits even in peacetime. A more robust public health system will be better able to cope with emerging infections and the consequences of natural disasters.

A half century ago, in response to another national security threat, the United States embarked on a research and development program designed to "send a man to the moon and bring him back within this decade." Given America's scientific talent and the extraordinary progress being made in life sciences research, it is conceivable that we could make enough progress in the understanding and treatment of infectious diseases to render biological weapons effectively obsolete as weapons of mass destruction.

In pursuing such an aim, we would undoubtedly also learn much that could diminish the scourge of infectious disease in developing countries – where they account for half of all premature mortality. The National Intelligence Council has written that this overburden of infectious disease- which accounts for account for half of all premature mortality in the developing world -is hampering some nations' transition to democracy. Lessening this burden would be a worthy humanitarian goal – and might also address some of the despair on which the plague of terrorism feeds.